Template for Study Proposal

(For scientific review committee)

How to use this template:

The template (the table on page 3) provides ALL the sections, headings and subheadings that you will require in your proposal, as well as the line and paragraph spacing, page breaks, page numbering, referencing system and referencing styles. You should simply type (mostly in column 2) and insert your own text as per your proposal, i.e simply type into the document (Delete the content of the cells in column 3 as those are the instruction about the particular row and afterwards the space will be used for the review and comments by the review committee.).

Do not attempt to change the styles for the headings or subheadings, and do not attempt to use more than three level headings (i.e. A main heading, a sub-heading and a sub-sub-heading). Do not write anything in column 3 as the same is made for scientific review committee.

WHEN YOU ARE DONE, DELETE THIS FRONT INSTRUCTION PAGE FROM YOUR PROPOSAL

Proposal and all related documents should be submitted to as zip file: irb_gmcb@yahoo.com

During submission of proposal, you have to create two different folders and name them as:

A. PI name_Department_SRC B. PI name_Department_IRB.

Each folder should have following documents:

A. PI name_Department_SRC:

1. **IRB form (Latest version)**
2. **Study Proposal in MS Word format (In the prescribed attached format)**
3. **Power point presentation in MS power point format (Max 10 slides; Font size 28 - Title, Introduction (1 slide), Aims/Objectives, Methods in detail, Dummy Tables - with title of the table and also of each row and column)**
4. **Case Record Form/ Study questionnaire in MS Word format**
5. **Patient Information Sheet & Informed Consent Form in MS Word format (English & Gujarati)**

6. **Scanned/downloaded copies of relevant/cited articles in PDF format**
7. **Investigator's brochure (For regulatory trial)**

B. PI name_Department_IRB:

1. **CV of all investigators in PDF**
2. **GCP training certificates in PDF**
3. **Medical Registration certificates in PDF**
4. **CTRI Reference number copy in PDF**
5. **Departmental Scientific Discussion attendance sheet (Scanned PDF copy)**
6. **DCGI approval letter (For regulatory trial)**
7. **Copy of insurance policy (For regulatory trial)**
8. **Clinical trial agreement draft copy (For Regulatory trial)**
9. **Participant diary (For regulatory trial)**

Submission will be considered as valid when,

1. All the required documents will be received as two different zip folders in single email.

2. Email will be received from email id of PI mentioned in IRB form and Proposal form.

3. Inadequate documents in single email, documents sent through multiple emails, receipt of email other than mentioned email id of PI in IRB form and proposal form will be not be considered and entertained.

PROPOSAL FOR THE SCIENTIFIC REVIEW

Title of the Project/Thesis/Dissertation:

Name of the Student/ Principal Investigator:

Department(s):

Mobile No.: **E-mail ID:**

Name(s) of the PG Guide/Co-investigator(s) :

No.	Name with Designation	Mobile	Email	Sign (in Hard Copy)
1				
2				
3				

Heading	Details	Instructions / Comments
Title		Neither too short nor too long.Indicate the study's design with a commonly used term. Should be concise yet descriptive, informative and catchy. The title may need to be revised after completion of writing of the protocol to reflect more closely the sense of the study.
Introduction & review of Literature (Justification) Max 750 words		**Why do you want to conduct this study?** Provide background information for the research (i.e. the problem being addressed) and is typically structured from general information to narrow or focused ideas; whereupon your research question/s or hypotheses are presented. Imagine you are writing for a general science reader rather than an expert audience. The Introduction includes a brief review of relevant literature or knowledge in the field, so that you are able to present the gap in the existing knowledge and, therefore, the

		significance and originality – the purpose and aims – of your research (how your study will fill the gap in the existing knowledge). Use a plethora of sources especially primary sources such as journal articles. Textbooks, web sites (with great caution) and personal communications with professors can also be useful sources. Make sure to cite appropriately in the text. For Citations, your sentence structure should look something like this: (Vancouver style) *Caitlin J, Rose W, Maureen O'L, Elisabeth E, Heidi JL. Strategies for addressing vaccine hesitancy – A systematic review. Vaccine 2015;34:4180-90.* *For detail: https://guides.lib.monash.edu/citing-referencing/vancouver* Never leave your reader in doubt as to the source of your information! Cite thoroughly and cite properly

Research Question		You should be very clear about it as your whole study design will depend on this. The research question should pass the FINER test! FINER means feasible, interesting, novel, ethical and relevant. Feasibility is the most important criteria (that is, you should be able to include sufficient number of patients in the given time span of data collection). Ethical means follows the principles of ethics in research (like doing no harm to patients, etc.). Relevant means which is useful to the scientific community and helps in advancement of existing scientific knowledge. **Examples of research questions:** **Among children of Bhavnagar district, what is the difference in the level of protection by a new vaccine between vaccinated and non-vaccinated children?**
Aim/Goal		**What do you want to find at the end of study?** It is a statement of the hypothesis, usually derived from the research question. Generally it is broader than the objectives.

		For example, *to determine whether or not a new vaccine should be incorporated in a public health program.*
Objectives: Primary Secondary		Research objectives are the goals to be achieved by conducting the research. The specific objectives relate to the specific research questions the investigator wants to answer through the proposed study and may be presented as primary and secondary objectives, **for example - primary:** ***To determine the degree of protection that is attributable to the new vaccine in a study population by comparing the vaccinated and unvaccinated groups.*** - **Secondary:** ***To study the cost-effectiveness of this programme.*** **Don't put too many objectives or over-ambitious objectives that cannot be adequately achieved by the implementation of the protocol.**

Methodology		
Study design/type		Only name of the design - Cross-sectional, cohort, case control, randomized or non-randomized controlled trial, etc. **As per CTRI**
Study population		Target population to whom your result will be applied
Sample size		Number of study participants
Study duration		Time required in months (after IRB approval till submission of the thesis/report)
Study site		Place of study
Study procedures: Details of procedures along with Inclusion & exclusion criteria Details of study groups, intervention,		• Brief description of the broad research approach (qualitative or quantitative or mixed method) drawing on some evidence to justify the appropriateness of the proposed research approach. • Brief outline of the research setting, methods of data collection (example survey, qualitative interviews etc.),

follow up, randomization, blinding, etc		who the participants would be and a brief explanation of how participants will be accessed. • Identifying minimum sample size required would be helpful. • Sampling technique • Most important aspect for this section is the alignment and appropriateness of the research approach. Research approach and data collection methods must align well with the problem, the research aim and research hypothesis/question. Proposed research approach and methods of data collection must be appropriate to the research aim. • If this research is a part of a bigger research project, provide a brief description of the overall research project and a brief explanation of how this proposed research fits into the bigger research project. Describe your proposed experiment in depth. What processes are you going to use? What kind of equipment and supplies will be necessary for the project? What will you use

		for a control, and what will be your replicate? Be thorough, but not excessive. It might be useful to construct an outline before completing this section, as this will give you an idea of what should be occurring when, and if your goals are attainable in the given time.
Outcome variables		During the planning stage, it is necessary to identify the key variables of the study and their method of measurement and unit of measurement must be clearly indicated. Four types of variables are important in research. a. Independent variables: variables that are manipulated or treated in a study in order to see what effect differences in them will have on those variables proposed as being dependent on them. The different synonyms for the term ‘independent variable’ which are used in literature are: cause, input, predisposing factor, risk factor, determinant, antecedent, characteristic and attribute. b. Dependent variables: variables in which changes are results of the level or amount of the independent variable or variables.

		Synonyms: effect, outcome, consequence, result, condition, disease. c. Confounding or intervening variables: variables that should be studied because they may influence or ‘mix’ the effect of the independent variables. For instance, in a study of the effect of measles (independent variable) on child mortality (dependent variable), the nutritional status of the child may play an intervening (confounding) role. d. Background variables: variables that are so often of relevance in investigations of groups or populations that they should be considered for possible inclusion in the study. For example sex, age, ethnic origin, education, marital status, social status etc. The objective of research is usually to determine the effect of changes in one or more independent variables on one or more dependent variables. For example, a study may ask "Will alcohol intake (independent variable) have an effect on development of gastric ulcer (dependent variable)?" Certain variables may not be easy to identify. The characteristics that define these

		variables must be clearly identified for the purpose of the study. **Details of screening study/sentivity/specificity**
Statistical methods Data analysis plan: Type of data, how data will be compared? selection of statistical test		Why do we need all these? Instead, we can only ask for dummy tables…...
· Dummy table		Not here Include this in power point presentation.
List of References		As per vancouver style: You can use mendeley, zotero, endnote softwares for reference management